

June 5, 2017

National Association of Boards of Pharmacy® (NABP®)
ATTN: Ms. Dawn Bibbs-Morrissey
1600 Feehanville Drive
Mount Prospect, Illinois 60056

Dear Ms. Dawn Bibbs-Morrissey,

Please accept this email as an official request for the NABP to accept and consider Safe Chain Solutions' reapplication for VAWD Accreditation. We are wholly committed to the Accreditation process and being compliant with all VAWD standards.

Per your email dated April 26, please find requested materials below and attached.

Reapplication Requirement 1 - Detailed evidence and summary of the due diligence performed to mitigate the cited non-compliance. This must include, at a minimum: a root cause analysis, a corrective action and preventive action plan addressing each area of non-compliance, and any supporting data that supports a CAPA that is already in place. The root cause analysis should follow a prespecified protocol that begins with data collection that must include specific non-compliant events located as a result of the investigation undertaken and reconstruction of the non-compliant events through record review and participant interviews. An analysis of the process sequence leading to the non-compliant event should occur that results in identifying how and why the event occurred.

RE: Root-Cause Analysis

As a result of the cancellation of our VAWD Application, the senior management team at Safe Chain Solutions has led an extensive review of sourcing practices. The result of our review revealed that Safe Chain Solutions has in fact accepted product with a pharmacy or pharmacy-wholesaler on the Transaction History as well as accepted product from sources that have not reported to the FDA as a wholesale distributor.

Specifically, our team found over 5 pharmacies or pharmacy-wholesalers on the Transaction History for past orders. In the same vein, these same entities were not registered. Please find the T3s for the violating orders attached as well as a summary list below of all violating entities.

- Dundalk Pharmacy
- Colora Pharmacy Shifa RX
- Don's Pharmacy
- JTW dba Milburn Pharmacy
- New Venture Pharmacy
- A Village Pharmacy



Accordingly, a handful of our vendors have also been “blacklisted” per the following:

- Pro Pharma Distributions
- KY Meds
- Medcare Health of NJ
- South Pointe Wholesale
- Harford Health
- HPC - RX

Product was accepted with these entities on the Transaction History simply because we were not actively monitoring the Transaction History with VAWD criteria; the lack of due diligence was a systematic failure on our part and we will strive to comply, moving forward.

RE: Corrective Action Plan

It is the intention of Safe Chain Solutions to strictly adhere to all VAWD Standards. As such, we have taken multiple steps to correct operational deficiencies.

- Safe Chain Solutions has implemented a policy where the T-3 for every order will be examined and approved by senior management or Katie Eberspacher, Compliance Manager, identify product with entities on the Transaction History that are not compliant with VAWD Standards.
- Updated our Vendor Agreement to reflect our new sourcing policies.
- Company meeting to make sure everyone understands the new policies and to ensure all employees are following the proper protocol with the new implementation.
- A preventive action plan addressing will be implemented using daily task changes:
 - Compliance Manager: Verify the Transaction History for every product that arrives in warehouse before it is assimilated into inventory.
 - Purchasing Manager: Weekly spot-check of Transaction History to ensure compliance.

RE: Supporting Data

- Updated “Source List”
- Updated Sourcing Policies and Procedures
- Transaction History with violating entities highlighted – demonstrates Safe Chain’s ability to identify violating entities.

Reapplication Requirement 2 - Revised, detailed policies and procedures as necessary to address all areas of non-compliance.

Please find attached to our reapplication; we have wholly revised sourcing authentication and verification per VAWD Criteria.

Reapplication Requirement 3 - A revised source list.

Please find attached.

Moving Forward

Thank you again for your consideration of our documentation and information regarding our renewed effort to abide by all VAWD standards. We look forward to working with you and the rest of the NABP team to earn VAWD Accreditation.

Regards,

Charles Boyd, President

Safe Chain Solutions